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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/290,049	04/12/1999	DANIEL J. SMITH	FDC98-01P2A	9419

7590

11/18/2003

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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/18/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/290,049

Applicant(s)

SMITH ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21August2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-23,25,28,33 and 81-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23,25,28,33,81-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.
2. Applicant's Amendment and Response, received 21August2003, paper#32, is acknowledged. Claims 12-14, 20, 24, 26-27, 31-32, 34-38, 41-48, 51-58, 61-68, and 71-78 have been cancelled. New claims 81-105 have been added.
3. Claims 21-23, 25, 28, 33, and 81-105 are pending.

### **Rejections Moot/Withdrawn**

4. The provisional rejection of claims 32, 35, 42, 45, 52, 55, 62, 65, 72, and 75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 14, and 15 of copending Application No. 09/562,328, is moot in light of the cancellation of the claims.
5. The rejection of claims 20, 24, 26, 27, 31, 34, 36, 37, 38, 41, 43, 44, 46, 47, 48, 51, 53, 54, 56, 57, 58, 61, 63, 64, 66, 67, 68, 71, 73, 74, 76, 77, and 78 under 35 U.S.C. 112, second paragraph, as being indefinite for the positions of the claimed amino acids, is moot in light of the cancellation of the claims.
6. The rejection of claims 26, 27, 36, 37, 46, 47, 56, 57, 66, 67, 76, and 77 under 35 U.S.C. 112, first paragraph, scope of enablement for constructs further comprising portion of pathogens, is moot in light of the cancellation of the claims.

### **Rejections Maintained**

7. The provisional rejection of claims 21, 22, and 25, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-15 of copending Application No. 09/562,328, is maintained for reasons of record.

Applicants argue that claims 12-15 of copending Application No. 09/562,328 have been withdrawn from prosecution and therefore, the instant rejection should be withdrawn.

The examiner has considered applicants' argument, but does not find it persuasive. While claims 12-15 of copending Application No. 09/562,328 have been withdrawn from prosecution, the claims remain pending. Until such time as the instant claims are amended or claims 12-15 of copending Application No. 09/562,328 are canceled, the rejection is maintained.

8. The rejection of claims 23, 28, 33, and newly added claim 105 under 35 U.S.C. 112, second paragraph, as being indefinite for the positions of the claimed amino acids, is maintained for reasons of record.

Applicants argue that the amendment of the claims obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. Independent claim 21 as currently amended recites "An immunogenic composition comprising  $\geq 1$  peptide which is an amino acid sequence subunit of glucosyltransferase of 15-21 amino acids in length comprising an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, and SEQ ID NO:19."

Newly added claim 105 would have been included in the original rejection. Therefore, it is included at this time for the same reasoning.

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The amendments of claims 23, 28, and 33 remain indefinite for the position of the claimed amino acids because there is no requirement that the amino acids be a part of any of the recited SEQ ID Nos.

### **Claim Rejections - 35 USC § 112**

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 21-23, 25, 28, 33, and 88-105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a composition comprising  $\geq 1$  peptide which is an amino acid sequence subunit of glucosyltransferase of 15-21 amino acids in length comprising an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, and SEQ ID NO:19.

However, SEQ ID NO:3, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, and SEQ ID NO:19 are sequences of 22 amino acids in length. Therefore, it is unclear how one has an amino acid subunit of glucosyltransferase **of 15-21 amino acids in length** comprising a larger amino acid sequence, i.e., 22 amino acids in length.

### **Double Patenting**

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 23, 28, 33, and 81-105 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-15 of copending Application No. 09/562,328. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a composition "comprising"  $\geq 1$  peptide comprising SEQ ID NO:1, 2, 3, 10, 11, 12, 13, 14, 15, 16, 17, 18, and 19 which are identical to SEQ ID NO:20, 27, 22, 23, 24, 25, 27, 29, 29, 30, 31, 32, and 37 of copending Application No. 09/562,328. The use of open language "comprising" encompasses single peptides and conjugates of which one part is the recited peptide sequence. Claims 12, 13, 14, and 15 of copending Application No. 09/562,328 are drawn to a such a

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composition comprising a conjugate of  $\geq 1$  glucan and  $\geq 1$  moiety, wherein the moiety comprises SEQ ID NO:20, 27, 22, 23, 24, 25, 27, 29, 29, 30, 31, 32, and 37.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### Conclusion

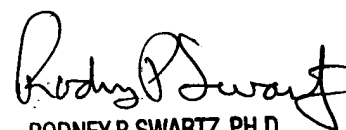
14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244.

The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

November 17, 2003